DIASOL, INC.

5. 510(k) Summary

FEB 10 2014

SUBMITTER:	DIASOL, INC 1110 Arroyo St San Fernando, CA 91340 Tel: 818-838-7077 Fax: 818-838-7007
CONTACT:	MONICA ABELES
DATE SUMMARY WAS PREPARED:	December 6, 2012
CLASSIFICATION:	GASTROENTEROLOGY/UROLOGY
REGULATION NUMBER:	21 CFR 876.5820 Hemodialysis system and accessories
CLASSIFICATION PRODUCT CODE:	KPO
NAME OF DEVICE:	CITRISOL ACID CONCENTRATE
COMMON NAME:	ACID CONCENTRATE FOR HEMODIALYSIS USE 21 CFR 876.5820 Hemodialysis system and accessories CLASS II
CLASSIFICATION NAME:	ACID CONCENTRATE FOR HEMODIALYSIS USE 21 CFR 876.5820 Hemodialysis system and accessories CLASS II
PREDICATE DEVICE:	Diasol Acid concentrate K854391 Dryasol Concentrate K993212 Citrapure K062399 Citrasate K000792

SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

DIASOL. INC.

CitriSol is manufactured following strict cGMP's and in accordance with the AAMI/ANSI/ISO 13958:2009 concentrates for hemodialysis and AAMI/ISO/ANSI 13959:2009 Water for Hemodialysis.

Our product codes are easy to understand. They identify the electrolytes present in each solution. Preceded by CS representing the Citric Acid part.
In the 45x proportioning formulations the first three numbers -100 stand for the Na, followed by K (ex 2), Ca (25), -Mg (75)
This example stands for CS 100225-75 a 2K 2.5 Ca product.

CitriSol acid concentrate comes in liquid and dry powder form. The product is available in all 3 different proportioning, as shown in the table below:

45X LIQUID CITRISOL FORMULATIONS	36.83X LIQUID CITRISOL FORMULATIONS	35X LIQUID CITRISOL FORMULATIONS	POWDER CITRISOL FORMUALTIONS
100020-75-DEX100	80020-75-DEX100	78020-75-DEX100	
100120-75-DEX100	80120-75-DEX100	78120-75-DEX100	
100220-75-DEX100	80220-75-DEX100	78220-75-DEX100	
100320-75-DEX100	80320-75-DEX100	78320-75-DEX100	
100420-75-DEX100	80420-75-DEX100	78420-75-DEX100	**ALL**
100025-75-DEX100	80025-75-DEX100	78025-75-DEX100	**FORMULATIONS**
100125-75-DEX100	80125-75-DEX100	78125-75-DEX100	**AVAILABLE**
100225-75-DEX100	80225-75-DEX100	78225-75-DEX100	**IN**
100325-75-DEX100	80325-75-DEX100	78325-75-DEX100	**POWDER FORM**
100425-75-DEX100	80425-75-DEX100	78425-75-DEX100	**ALSO**
100030-75-DEX100	80030-75-DEX100	78030-75-DEX100	
100130-75-DEX100	80130-75-DEX100	78130-75-DEX100	
100230-75-DEX160	80230-75-DEX100	78230-75-DEX100	
100330-75-DEX100	80330-75-DEX100	78330-75-DEX100	
100430-75-DEX100	80430-75-DEX100	78430-75-DEX100	
100035-75-DEX100	80035-75-DEX100	78035-75-DEX100	
100135-75-DEX100	80135-75-DEX100	78135-75-DEX100	
100235-75-DEX100	80235-75-DEX100	78235-75-DEX100	
100335-75-DEX100	80335-75-DEX100	78335-75-DEX100	
100435-75-DEX100	80435-75-DEX100	78435-75-DEX100	

CitriSol acid concentrate dry powder or liquid is indicated for use in the acute and chronic Hemodialysis. It is an accessory to be used with the appropriate Hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO standard water for hemodialysis and Sodium Bicarbonate Mix.

CitriSol, contains all the same electrolytes as Diasol Concentrate and 2.4mEq of Citric Acid.

CitriSol, when mixed with ANSI/AAMI/ISO standard water for hemodialysis, has the same chemical equivalency as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2014

Diasol, Inc.
Monica Abeles
President
1110 Arroyo Street
San Fernando, CA 91340

Re: K130511
Trade/Device Name: CitriSol acid concentrate
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: December 9, 2013
Received: December 11, 2013

Dear Monica Abeles,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130511

Device Name: Citrisol Acid Concentrate

Indications For Use:

CitriSol acid concentrate dry powder or liquid is indicated for use in the acute and chronic Hemodialysis. It is an accessory to be used with the appropriate Hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO standard water for hemodialysis and Sodium Bicarbonate Mix.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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